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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/782,015	02/12/01	CHEIN E	00115P002D

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HM12/0906
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EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1653	4

DATE MAILED: 09/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/782,015	Applicant(s) Chein
	Examiner F. MOEZIE	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *2/12/01 and 7/3/01* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *10-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *10-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

STATUS OF CLAIMS

Claims 10-17 are pending prosecution in this Office action.

REJECTION - 35 U.S.C. 112, SECOND PARAGRAPH

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "treating symptoms associated with multiple sclerosis" render the claim indefinite as to the symptom(s) being treated.

The terms "predetermined physiological levels" (claims 10-13) and "physiological levels associated with the second or third decades of an average human subject" (claims 14-17) render the claims indefinite as to the claims metes and bounds. What are the levels that a patient or a practitioner is trying to reach in a patient in need of the treatment.

The term "less than" (claims 11 and 15) is a relative term and renders the claim indefinite as to the claim metes and bounds.

Claims 10-17 are improper kit claims. The claims are drawn to a composition comprising hGH and a second hormone. The claims lack a proper (packaging) label that instructs the user to dissolve the hormone(s) in the diluent(s) and use the composition within a

certain length of time including the method of using the composition - either separately or concomitantly by different routes.

REJECTION - 35 U.S.C. 103 (a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danielov US 5,885,974 - filed Dec. 6, 1994.

Danielov teaches compositions and kits comprising a hGH, progestrone, luteinizing Hormone and various other hormones for treating a patient. See col. 14, lines 1-28. Furthermore, the content of the commercial kits comprising somatotropin and sex hormones are shown at column 20, lines 15+. Finally, the claims are drawn to a kit comprising somatotropin, luteinizing hormone and thyrotropic hormone among others (claims 9). See the entire document.

Because the claims are drawn to a (kit) composition comprising the therapeutic components taught by the art, the claims are unpatentable in view of the art.

OBVIOUSNESS DOUBLE-PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-34 of U.S. Patent No. 5,855,920. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent as shown in the specification and the claims

CONCLUSION

No claim is allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. LOW (SPE) at 308-2923.

F. T. Moezie
MOEZIE
PRIMARY EXAMINER
ART UNIT 1653